DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAY 5 2005

0955 5 MAY 12 A4:53

Beth Rosenshein
12819 SE 38th Street, #34
Bellevue, WA 98006

Re: Docket No. 2004P-0513/CP1

Dear Ms. Rosenshein:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition submitted on November 17, 2004. Your petition requests that the Agency make two changes to the labeling for Premarin (conjugated estrogens) tablets: (1) update the black box warning to recognize significant prolonged levels of equilin after withdrawal of estrogen therapy, and (2) add statements to the warnings section of the labeling on the accumulation of equine estrogens during Premarin therapy.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0513 LET 1